OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE **http://www.niaid.nih.gov/contract/default.htm** FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***	***Small Bus. Set-Aside*** [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [X]No NAICS Code: 541710 Size Standard: 500 Employees	***Level of Effort:*** [ ] Yes [X] No Total Effort: [N/A]
NIH-NIAID-DAIDS-02-19	[ ] Yes [X] No		

TITLE: **Drug Development for Opportunistic Infections – Cell and Animal Model Development for Hepatitis C**

Issue Date:	***Due Date:*** November 15, 2001 ***Time:*** 4:00 PM, EST	***Technical Proposal Page Limits:*** [X] Yes (see "How to Prepare and Submit Electronic Proposals") [ ] No
August 15, 2001		

ISSUED BY:

Paul D. McFarlane, Contracting Officer
Contract Management Branch, DEA
NIAID, NIH
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

[X] We reserve the right to make awards without discussion.

NO. OF AWARDS:	***PERIOD OF PERFORMANCE:***
[ ] Only 1 Award [X] Multiple Awards	Seven (7) years beginning on or about 07/15/2002

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE

POINT OF CONTACT -- Scott Drega --COLLECT CALLS WILL NOT BE ACCEPTED--

Telephone: Direct 301-496-6424 ***Main* 301-496-0612**	***Fax* 301-402-0972**	***E-Mail* SDrega@niaid.hih.gov**

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Background
Drug Development for Opportunistic Infections
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The purpose of this contract is to support the National Institute of Allergy and Infectious Diseases (NIAID) in its mission to stimulate research towards discovery of improved therapies for hepatitis C, an infectious disease associated with the acquired immunodeficiency syndrome (AIDS) and an increasing public health problem. This solicitation is unique and independent from other previous NIAID initiatives that sought to support the development of animal models of hepatitis infection.

The increasing incidence of chronic liver disease due to hepatitis C, particularly in conjunction with infection with the human immunodeficiency virus (HIV), has contributed to a public health emergency. Infection with hepatitis C virus with or without HIV co-infection has produced an important medical challenge due to the limited treatment options for hepatitis C. Limited efficacy and substantial adverse reactions to therapy are currently seen with state-of-the-art combination therapy for hepatitis C. The development of new therapeutics for hepatitis C is hampered by the lack of both in vitro and in vivo models of hepatitis C virus replication and pathogenesis.

In order to facilitate the development of improved anti-viral therapeutics for hepatitis C, NIAID requires the directed acquisition and evaluation of cell-culture in vitro models of hepatitis C virus infection and replication, as well as, animal models of hepatitis C disease. It is anticipated that the developed models of hepatitis C virus replication, infection and/or pathogenesis will be utilized to test selected novel synthetic and pure natural product compounds as potential hepatitis C anti-virals. It is envisioned that test compounds will be submitted under confidentiality agreements by pharmaceutical houses or research institutions in exchange for potential therapeutic information on the relative potency of their compounds as anti-virals versus hepatitis C. The ultimate goal of this effort will be to encourage the rapid and efficient exploration of new classes of compounds for development as potential anti-hepatitis C agents.

Two contracts will provide the facilities for coordination of biochemical, cell and /or animal model development, acquisition and data management, biochemical, and cell and/or animal efficacy testing.

The contract awarded under Part A will serve as the central facility for *in vitro* cell-culture model development and testing of novel compounds. This assay may seek to achieve hepatitis C virus replication in a cell-culture environment and to screen novel compounds for the inhibition of viral proliferation (cellular infectivity) and/or replication *in vitro*. This assay should be adaptable to the testing of large number of compounds using high-throughput formats and is likely to identify compounds for testing in Part B.

The contract awarded under Part B of this solicitation will provide animal model development and testing of novel compounds previously showing efficacy using *in vitro* assay systems. The contracts will be interactive, are likely to exchange data at regular intervals, and will formulate directions for testing in conjunction with the Project Officer.

Because of the critical public health need to identify and develop new candidate drugs to combat hepatitis C, the highly technical nature of the work required, and the numerous assays producing critical information, close coordination of the Contractors' efforts by the Project Officer will be necessary.

The work statement contains two parts, with a separate work statement for each part. Offerors shall submit completely separate proposals in response to Part A and/or Part B . Offerors may respond to more than one Part, but must submit separate Technical and Business Proposals for each (under separate cover) to be considered. For each Part, separate Technical Evaluation Criteria will apply and separate competitive ranges will be determined. If submitting for multiple Parts, Offerors must clearly describe how work under each Part will be coordinated. Part A and Part B proposals will be evaluated independently.

Statement of Work
Drug Development for Opportunistic Infections
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Part A

Cell Culture Model Systems/Assays for Hepatitis C

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the work described below.

Specifically, the Contractor shall:

1. Develop, test, validate, and standardize novel model system(s)/assays of hepatitis C virus replication and /or infection suitable for the testing of the efficacy of anti-viral agents.

The model system(s)/assays developed shall be applicable to test novel agents either in vitro or as first step for in vivo testing (Work Statement, Part B) to determine efficacy of anti-viral agents in preventing hepatitis C virus infection and thereby provide selective, sensitive and reproducible data for analysis. The efficacy can be determined as the inhibition of hepatitis C virus cellular infectivity and/or inhibition of hepatitis C replication. (See Note to Offeror #1)

a. Design, develop and test assays to determine the biology (biochemistry, virology, molecular biology) of the inhibition of hepatitis C infectivity and/or replication and relevance to the hepatitis C virus infection.

b. For biochemical ligand-inhibitor, target-specific screening assay(s) based on a defined element(s) of the hepatitis C virus life cycle, determine the biochemistry of the ligand-inhibitor interaction and relevance to the hepatitis C virus life cycle

c. Test sample inhibitor compounds to validate assay systems. Determine concentration range of test compounds and level of inhibition of infection.

d. Determine the cytotoxicity of compounds, identified as active in Work Statement 1.1 for actively dividing mammalian cells (IC_{50}).

2. Improve, standardize, and adapt new assays for determining the activity of compounds against hepatitis C virus.

Adapt and standardize new assays based on advances in the field, as approved by the Project Officer, to increase testing efficiency and to employ the latest technological developments such as:

a. Develop or adapt a validated assay to a high-throughput format (defined as 96 or more reaction wells arranged for simultaneous testing and operation by computer-directed systems).

b. Screen libraries of synthetic compounds as potential anti-hepatitis C agents for use in treatment regimens. Compounds shall be provided to the Contractor by the Project Officer.

c. Assemble data into computer formats compatible with existing NIAID Drug Development data (see attached notes).

3. Provide safe facilities and resources. (See Note to Offeror #6)

a. Conduct work in accordance with the clause outlined under "Safety and Health" – HHSAR

352.223-70".

b. Conduct work under this contract under Biosafety Level Guidelines when appropriate and in accordance with all applicable Federal, State and Local laws, codes, ordinances and regulations, and with basic references and related modifications. (See "Safety and Health" – HHSAR 352.223-70")

c. Provide facilities and equipment to receive, store, and manipulate hepatitis C and potentially hazardous compounds and maintain their stability.

d. Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous microorganisms and materials. Specifically, the Contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein.

e. Assure that no identifiable data on the compounds or products and the results of testing will be kept in files open to the public, and that facilities for computer operation, data entry, and file storage are secure from unauthorized access. Only those contract employees or Government employees directly engaged in this project shall have access to the files of information regarding source and nature of confidential or proprietary materials and results of testing.

4. Receive, store, and record compounds.

Develop and maintain efficient, effective procedures for documentation of receipt of compound shipments from the Project Officer. Provide for a computerized inventory of compound identifiers, amounts available, storage locations, and standardized microbiological activity.

5. Provide reports and meet with the Project Officer. (See Note to Offeror #7)

a. Report data generated under this contract to the Project Officer in the form of quarterly progress reports and annual reports as described in the contract Reporting Requirements (written reports and computer files).

To facilitate timely transmission of data and information, the Contractor shall establish and maintain an efficient data management system and electronic communication (electronic mail) with the Project Officer's office

b. The Contractor's Principal Investigator and key personnel shall meet with the Project Officer at periodic intervals, to be scheduled after contract award, to review progress, anticipated or existing problems, and discuss the work to be performed.

c. At least one of the Contractor's key personnel must attend and present information at one NIAID-sponsored meeting per year, at the direction of the Project Officer, on the compounds acquired and analyzed under the Contract.

6. Maintain confidentiality of data. (See Note to Offeror #8)

The Contractor shall be bound by the same terms as the Government with respect to the confidential nature of information provided by contributing suppliers. (See note to Offeror regarding deviation for FAR Clauses). The Contractor shall provide advance copies of draft manuscripts for publication (including abstracts and public presentations) based on data generated under this contract to the Project Officer, and obtain clearance before submitting for publication or presentation. Support from the Government contract must be acknowledged in all abstracts, presentations, and publications.

7. Ensure an orderly transition to a successor Contractor.

By the end of the sixth year of this contract, the Contractor shall have developed and submitted procedures for an orderly transition of data and samples to a subsequent Contractor or to the

Government, subject to Project Officer approval, and shall deliver, if requested by the Project Officer and by the expiration date of the contract, the following items: original data and any necessary information related thereto, and any Government-owned property, if applicable.

Part B

Animal Model Development for Hepatitis C

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the work described below.

Specifically, the Contractor shall:

1. Develop, test, validate, and standardize small animal model(s) of hepatitis C virus infection and/or hepatitis C-induced pathogenesis. (See Note to Offeror #2)

a. The model system(s) developed shall use small animals, either non-primates or small primates, and a clinical isolate of hepatitis C, genotype 1 or a genetically modified version of hepatitis C genotype 1.

b. Validation of the model must include demonstration of efficacy using the current combination therapy for human hepatitis C virus infection

c. The model will be applicable to test novel agents in vivo to determine efficacy of anti-viral agents in preventing the progression of acute hepatitis C infection or preventing and /or ameliorating chronic hepatitis C –induced pathogenesis.

d. The model will identify correlates of infection and /or correlates of chronic liver disease that are suitable for determining efficacy, in a limited time frame, in reducing hepatitis C virus infection and/or pathogenesis by novel therapeutic compounds.

e. Further characterize and improve model utility, including use for immunocompromised settings.

2. Evaluate compounds against hepatitis C virus infection in vivo (See Note to Offeror #3)

Following validation of the model, evaluate approximately 20 compounds per year against established hepatitis C (genotype 1 clinical isolate or genetically modified infectious virion) infection using the standardized, validated animal model of infection. During the term of the contract, candidate therapeutic agents will be supplied by the Project Officer. The Contractor shall also identify and propose agents to the Project Officer for evaluation. The Contractor shall provide individual experimental protocols to the Project Officer for approval prior to performing animal evaluation studies.

The in vivo evaluation system for efficacy of a candidate compound shall include the following:

a. Quantitative assessments which detect statistically valid differences between treatment groups of animals of hepatitis C viral load (and other correlates of infection and/or pathogenesis identified in Part A 1.1.d) present in serum and tissues of infected animals. In addition, assessment of hepatitis C viral diversity present in serum and tissues of infected animals, and selected indicators of morbidity;

b. Microbiological and histological analyses, including but not limited to special stains and cultures, to document the in situ localization of hepatitis C virus, pathology, severity of infection , location of the animal infection and viral diversity;

c. Appropriate observations and measures of general toxicity, to include body weight and daily assessment of appearance and general health, obtained during efficacy studies;

d. A standardized, validated protocol for testing new therapies against an active infection of hepatitis C with a proven agent identified as a positive control drug.

3. Perform specialized evaluations (See Note to Offeror #4)

Design protocols and perform additional studies approved by the Project Officer for more detailed evaluation of promising therapies in the primary animal model.

These studies shall include, but are not limited to:

a. Comparison of quasispecies of hepatitis C virus in efficacy evaluations ;

b. Confirmation of drug efficacy against hepatitis C virus infection in vitro;

c. Determination of optimal dosages, routes and schedules of administration of therapies;

d. Determination of achievable plasma and tissue levels, including estimation of maximum plasma concentrations, approximate plasma half-life, and bioavailability of new therapies.

Propose and perform experiments, upon approval by the Project Officer, that characterize and/or modify the animal model or develop other models to improve model utility in the evaluation of therapies for use in the setting of immunocompromised hosts.

4. Prepare samples (See Note to Offeror #5)

At the specific request of the Project Officer, obtain and preserve samples of purified virus or animal tissues and fluids. Samples shall be sent, at the direction of the Project Officer, to another investigator who may perform additional experiments with the samples or may analyze samples for drug or metabolic concentrations. The Contractor shall cooperate or collaborate with other investigators as requested.

5. Provide safe facilities and resources. (See Note to Offeror #6)

a. Conduct work in accordance with the Federal Guidances related to workplace safety which can be viewed at the website: http://www.nih.gov/od/ors/ds/safetymgt.html.

b. Conduct work under this contract under Biosafety Level Guidelines when appropriate and in accordance with all applicable Federal, State and Local laws, codes, ordinances and regulations, and with basic references and related modifications as noted in the Federal Guidelines for Research Involving Recombinant DNA Molecules which can be found a the website: http://www4.od.nih.gov/oba/guidelines.html.

c. Provide facilities and equipment to receive, store, and manipulate potentially hazardous compounds and maintain their stability.

d. Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous microorganisms and materials. Specifically, the Contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein.

e. Insure that no identifiable data on the compounds or products and the results of testing will be kept in files open to the public, and that facilities for computer operation, data entry, and file storage are secure from unauthorized access. Only those contract employees or Government employees directly engaged in this project shall have access to the files of information regarding source and nature of confidential or proprietary materials and results of testing.

6. Provide reports and meet with the Project Officer. (See Note to Offeror #7)

a. The Contractor shall report data generated under this contract to the Project Officer in the form of quarterly progress reports and annual progress reports as described in the contract Reporting Requirements (written reports and computer files). To facilitate timely transmission of data and information, the Contractor shall establish and maintain an efficient data management system and electronic communication (electronic mail) with the Project Officer's office.

b. The Contractor's Principal Investigator and key personnel shall meet with the Project Officer at periodic intervals, to be scheduled after contract award, to review progress, anticipated or existing problems, and discuss the work to be performed.

At least one of the Contractor's key personnel must attend and present information , at the direction of the Project Officer, on therapies evaluated under the contract at one NIAID-sponsored meeting per year.

7. Maintain confidentiality of data (See Note to Offeror #8)

The Contractor shall be bound by the same terms as the Government with respect to the confidential nature of information provided by contributing suppliers. (See note to Offeror regarding deviation for FAR Clauses). The Contractor shall provide advance copies of draft manuscripts for publication (including abstracts and public presentations) based on data generated under this contract to the Project Officer, and obtain clearance before submitting for publication or presentation. Support from the Government contract must be acknowledged in all abstracts, presentations, and publications.

8. Receive, store, and record compounds.

Develop and maintain efficient, effective procedures for documentation of receipt of compound shipments from the acquisition contractor or the Project Officer. Provide for a computerized inventory of compound identifiers, amounts available, storage locations, and standardized microbiological activity. Provide an inventory of biological specimens and samples including serum samples and stored tissues.

9. Ensure an orderly transition to a successor Contractor.

By the end of the sixth year of this contract, the Contractor shall have developed and submitted a plan or written procedures for an orderly transition of data and samples to a subsequent Contractor or to the Government, subject to Project Officer approval, and shall deliver, when requested by the Contracting Officer and by the completion date of the contract, the following items: accurate and updated protocols and databases; a final list of all therapies tested and all test results; an inventory of government-purchased equipment; all original data, preserved strains, cell lines, and samples; and any necessary documentation and instructions related thereto.

Notes To Offerors
Drug Development for Opportunistic Infections
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GENERAL NOTE TO OFFEROR: In responding to this RFP, Offerors must describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. Documentation shall also be provided on the qualifications, experience, education, competence, availability, and decision-making authority of the Principal Investigator, key personnel, and technical and support staff. Offerors must provide necessary facilities, including all major equipment, and capabilities to perform all the functions of the Work Statement.

It is understood that no single institution may have the expertise and facilities required to perform all items in the work statement, however, work statement item Part A, #1 or work statement item Part B, #1 may not be subcontracted. If a subcontractor is proposed for a component of the work statement, similar technical information shall be provided (as part of the proposal) as that required by the prime Contractor (i.e., technical approach, methods, experience, personnel qualifications, facilities, resources, etc.). Cost details shall also be provided by the subcontractor in the Business Proposal. The prime Contractor shall be responsible for all work performed under this contract including that performed by any subcontractor(s) proposed.

The handling and transportation of all reagents and Government-owned property under this contract shall be in accordance with all applicable Local, State and Federal regulations including health and safety standards (See Attachment A.1 to the Work Statement for details on health and safety standards).

NOTE 1 TO OFFEROR: This note is linked to work statement item #1 of work statement Part A.

During the course of the contract, assay protocols must be designed to test the efficacy of agents against hepatitis C virus infection and must include defined endpoints (function of components of the hepatitis C genome and/or life cycle stages; correlates of infection and/or pathogenesis; or indicators of morbidity). Technical proposals should include data supporting the reproducibility, standardization, and validation of the proposed assays.

For the purposes of preparing a cost proposal, Offerors should assume that therapeutic test compounds will be obtained by the Government through screening agreements with suppliers. The Offeror should not include costs of compound acquisition efforts, but should assume that a total of 1,000 to 4,000 individual compounds will be put forward for high throughput screening per year.

NOTE 2 TO OFFEROR: This note is linked to work statement item #1 of work statement Part B.

The term small primate excludes chimpanzees, rhesus monkeys and other primates weighing more than 2 kg when mature.

NOTE 3 TO OFFEROR: This note is linked to work statement item #2 of work statement Part B.

During the course of the contract, protocols must be designed to test the efficacy of agents against hepatitis C infection and must include defined endpoints (correlates of infection and/or pathogenesis) and indicators of morbidity. Technical proposals should include data supporting the reproducibility, standardization, and validation of the proposed model.

For the purposes of preparing a cost proposal, Offerors should assume that therapeutic test compounds will be obtained by the Government through screening agreements with suppliers. The Offeror should not include costs of compound acquisition efforts, but should assume that a total of 10 individual therapeutic agents at 3 dosages per compound will be evaluated per year, and that each evaluation will consist of 6 groups of animals treated as follows:

- One test therapy at 3 dosages, administered twice a day, for the duration of time appropriate to the proposed model;

- o A positive control, i.e., a recognized therapy with demonstrated efficacy for human hepatitis C infection;
- o A negative control, i.e., infected animals receiving no therapy; and
- o Toxicity controls, i.e., uninfected animals receiving the highest dosage of drug for the duration of the protocol.

For guidelines on the appropriate care of laboratory animals and institutional policies and responsibilities, the Offeror should consult the 1996 Edition of "Guide for The Care And Use Of Laboratory Animals" published by the Institute of Laboratory Animal Resources, National Research Council ISBN 0-309-05377-3 (Internet site -- http://www. .nap.edu/readingroom/books/labrats/)]. The Office of Laboratory Animal Welfare (OLAW, formerly Office for Protection from Research Risks, Division of Animal Welfare) at the National Institutes of Health, which has responsibility for the general administration and coordination of the Policy on behalf of the PHS, provides specific guidance, instruction, and materials to institutions that must comply with the Policy. For copies of supplemental materials, please contact OLAW at the National Institutes of Health, RKL1, Suite 1050, MSC 7982, 6705 Rockledge Drive, Bethesda, Maryland 20892-7982 (for express or hand delivered mail, use zip code 20817) or go to the website (–http://grants.nih.gov/grants/olaw/references/phspol.htm) for the October 2000 reprinting of the guidelines.

NOTE 4 TO OFFEROR: This note is linked to work statement item #3 of work statement Part B.

The main purpose of this project is performance of standardized evaluations of promising therapies for hepatitis C infection. If, and when, approved by the Project Officer, characterization and/or modification of proposed models will be done in place of therapeutics testing. Because the Government does not know if or what modifications are likely to be needed, this section should not be considered as part of the business proposal. It is expected that any necessary modifications of the model system will not increase the negotiated contract cost, but that existing resources will be redirected to accomplish this task. The Offeror should include documentation of qualifications, expertise, and strategies to modify models or develop new models for therapy comparisons.

NOTE 5 TO OFFEROR: This note is linked to work statement item #4 of work statement Part B.

For purposes of preparing a cost proposal, the Offeror should assume that 5 samples will be shipped per year to Bethesda, Maryland. Samples shall be preserved to maintain tissue and organism viability. TheOofferor should include the cost of all shipments in the cost proposal.

NOTE 6 TO OFFEROR: This note is linked to work statement items #3 of work statement Part A and #5 of work statement Part B.

The Offeror shall provide in the Technical Proposal the floor plan of the proposed facility and list equipment and resources dedicated to the project. The Offeror shall include a Safety and Health Plan for compliance with Biosafety Level Guidelines in the Technical Proposal and include a summary of the Offeror's safety and health operating procedures manual.

The DHHS safety and health clause "Safety and Health Deviation-HHSAR 352.223-70" will become an attachment to the solicitation and to the resultant contract. Written documentation from a Biosafety Officer (or equivalent) should be provided (e.g., a safety management program) to assure compliance with all safety guidelines and regulations, training and monitoring of personnel for exposure to infectious or hazardous reagents, and safe disposal of such agents.

NOTE 7 TO OFFEROR: This note is linked to work statement items #5 of work statement Part A and #6 of work statement Part B.

The Offeror should propose a plan for data management, analysis, and electronic digital communication with the

Project Officer. Communications should include the ability to transmit and receive electronic mail with the Division of AIDS computer network system. The Government will not authorize purchase of stand-alone computers under this contract for this purpose. The NIAID is connected to the Internet and uses IBM-compatible computer hardware for data management and communications. The Offeror should supply an IBM-compatible computer and should submit electronic reports in Microsoft Word[tm] version 7.0 for Windows and Microsoft Excel[tm] version 7.0 for Windows. See "Reporting Requirements And Deliverables".

For the purpose of preparing a cost proposal, assume 3 visits of one key personnel per year to 6700B Rockledge Dr, Bethesda MD 20892 to meet with the Project Officer and key personnel of the Division of AIDS and NIAID for one day, and attendance of one key personnel for four days at a programmatic meeting identified by the Project Officer be held in the greater Washington, D.C. area.

NOTE 8 TO OFFEROR: This note is linked to work statement item #6 of work statement Part A and #7 of work statement Part B.

A document titled Protection of Proprietary Data and one titled Screening Agreement for Submitting Products to the DAIDS, NIAID are attached to this solicitation. The first addresses the planned Contractor's handling of proprietary data acquired during the conduct of this contract. The second is provided for the Contractor's information only. It illustrates the type of agreement made between the DAIDS, NIAID, NIH and compound suppliers who may provide their compounds to the Contractor for in vitro testing. An Advance Understanding will be placed in the resulting contract to cover these issues. The Offeror is hereby notified that NIAID intends to place not only FAR clause 52.227-14 Rights in Data - General (June 1987) in the resultant contract, but FAR clause 52.227-14 Rights in Data - General (NIAID Deviation of NOV 1998). This latter clause is provided in full text as an attachment to this solicitation.

NIAID also plans to place FAR clause 52.227-11 Patent Rights - Retention by the Contractor (Short Form) (June 1989) in the resultant contract. In addition, NIAID is pursuing a formal determination of exceptional circumstances (DEC) to allow the placement of a FAR clause 52.227-11 Patent Rights - Retention by the Contractor (Short Form) (June 1989) (NIAID Deviation of NOV 1998) into the resultant contract. This clause deviation and the Rights in Data clause above would apply to routine screening activities involving the use of proprietary compounds provided to the Contractor by third party compound suppliers. The text of the deviated Patent Rights clause cannot be shared with the Offerors at this time. However, should NIAID be successful in obtaining a DEC, those Offerors whose proposals make the competitive range for award of the planned contract, will be given an opportunity to see the clause and understand its placement in the contract.

Reporting Requirements
Drug Development for Opportunistic Infections
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The Contractor shall submit technical progress reports covering the work accomplished during each reporting period. Distribution of written reports is listed below in D.

A. Quarterly Reports. By the fifteenth calendar day after completion of each quarter, the Contractor shall submit 2 paper copies of the progress report of work performed in the previous quarter AND 2 copies on magnetic media as computer files in Microsoft Word™ version 7.0 for Windows for text and Excel™ version 7.0 for Windows for tables and ISIS/Base format readable using an IBM-type personal computer. It remains the responsibility of the Contractor to assure receipt by the indicated government official listed below of all reports by the established due dates. A quarterly report is not required in the quarter that the final report is due.

Each quarterly report shall consist of:

1. A cover page containing:

   (a) Contract number and title;
   (b) Period of performance being reported;
   (c) Contractor's name and address;
   (d) Author(s); and
   (e) Date of submission.

2. A table of contents indicating page number for each major section.

3. Summary of available information on each therapy which was considered in designing the protocol.

4. Study protocol design(s), rationale, and results

5. Summary of all compounds acquired and test results obtained during the quarter.

6. Cumulative summary of all compounds acquired and test results obtained under the contract.

7. Summary of current technical or administrative problems encountered, their resolution or the proposed corrective action. Interpretation and brief discussion of data.

B. Final Report

The Contractor shall submit 2 paper copies of the final report which documents and summarizes the results of the entire contract for the period of performance AND as 1 copy on digital, magnetic media as computer files in Microsoft Word™ version 7.0 for Windows for text and Excel™ version 7.0 for Windows for tables readable using an IBM-type personal computer, or as specified by the Project Officer. This report will provide a final inventory and contain a cover page described in 1. above and the information required in 2. through 7. above. The final report shall be submitted one (1) month prior to the completion date of the contract.

C. Other Deliverables. The Contractor, subject to Project Officer approval shall deliver to the Government or its designee by the fourth year of the contract and subsequently as developed, the following items :

1. Samples of all reagents used in the development of assays and/or animal models to the NIAID AIDS Research Reference Reagent Repository;

2. A computer-generated listing of accurate and updated information on compound inventory, including activities of the Contractor, data files, original data and any necessary information related thereto;

3. Labeled and inventoried paper files; stored serum samples and tissues with an inventory

   The Contractor, subject to Project Officer approval shall deliver to the Government or its designee by the end of the sixth year or earlier as directed by the Project Officer:

4. Any other government-owned property;

5. The transition plan required in item #7, Part A and #9, Part B of the Work Statement;

6. One complete copy of the final, updated and verified Hepatitis C Database as a computer file;

7. A written assurance from the authorized institutional official that all files containing data relating to this contract have either been transferred or destroyed.

D. Technical Reports Distribution

Type of Report	No. of Copies	Addressee/Distribution	Due Dates
Quarterly	*1	Project Officer, OIRB, TRP, Division of AIDS, NIAID 6700-B Rockledge Drive Room 5108 MSC 7624 Bethesda, MD 20892-7624	quarterly
Quarterly	*Original	Contracting Officer, CMB, DEA, NIAID 6700-B Rockledge Drive Room 2230 MSC 7612 Bethesda, MD 20892-7612	quarterly
Final	*3	Same as Project Officer above	completion date
Final	*Original	Same as Contracting Officer above	completion date

* plus one copy on high density computer diskette or other digital medium approved by the Project Officer.

E. If the Contractor is unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR Clause No.	Date	Title
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Mar 2000	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)

52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program – Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	Oct 1995	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)

52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

DEVIATION TO FAR 52.227-14 Rights in Data – General (JUNE 1987)

This clause deviation applies to discoveries resulting from routine screening activities involving the use of proprietary compounds. Data resulting from research activities pertaining to the development of new screening assays or other activities involving the use of non-proprietary compounds will be covered by the standard Rights in Data clause [FAR 52.227-14 Rights in Data – General (June 1987)].

ADD THE FOLLOWING DEFINITION TO PARAGRAPH (a) OF THIS CLAUSE:

"Research compound" as used in this clause means patented or unpatented products or compounds to be used for screening and testing as anti-viral, anti-bacterial, anti-fungal, anti-parasitic, immunomodulating, and biological modifying agents with potential for the treatment of viral diseases including HIV and associated infections.

MODIFY PARAGRAPH (d) OF THIS CLAUSE TO READ:

(d) *Release, publication and use of data.* (1) The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except to the extent such data may be subject to the Federal export control or national security laws or regulations. However, in order that information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions, the Contractor will advise the NIAID Contracting Officer of any proposed publications or public disclosures relating to the work performed under this contract. Upon the NIAID Contracting Officer's request, the Contractor agrees to delay the public disclosure of such data or publication of a specified paper for a reasonable time specified by the Contracting Officer, not to exceed 6 months, to allow for the filing of domestic and international patent applications in accordance with Clause 52.227-11, Patent Rights (Deviation).

ADD THE FOLLOWING PARAGRAPH (j) TO THIS CLAUSE:

(j) Research products or compounds. The Contractor agrees that in accordance with paragraph (d)(2) proprietary information on research products or compounds, patented or unpatented, provided through this contract shall be used only for screening and testing as anti-viral, anti-bacterial, anti-fungal, anti-parasitic, immunomodulating, and biological modifying agents with potential for the treatment of viral diseases including HIV and associated infections and for no other purpose.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET - SUBMIT ON/BEFORE: Monday, October 15, 2001 (Attached to this listing)

[NOTE: Your attention is directed to the "proposal intent response sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:
http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- Technical Proposal Cover Sheet
- Technical Proposal Cost Information
- Summary of Related Activities
- Government Notice for Handling Proposals

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- NIH-2043, Proposal Summary and Data Record
- Small Business Subcontracting Plan Format [to be submitted only with a Final Proposal Revision if requested]
- Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours
- Offeror's Points of Contact

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts
- NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)
- Safety and Health, HHSAR Clause 352.223-70
- Report of Government Owned, Contractor Held Property
- Disclosure of Lobbying Activities, OMB Form LLL

PACKAGING AND DELIVERY OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. You are required to submit one original paper copy of your proposal along with the number of extra copies requested below.

ELECTRONIC SUBMISSION: In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the CRON. You must assure that all versions of the proposal are identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DAIDS-02-19
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, PERTINENT MANUALS, NONSCANNABLE FIGURES OR DATA, AND LETTERS OF COLLABORATION/INTENT).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If hand delivery or express service	If using U.S. Postal Service
Scott Drega Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Scott Drega Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with PHSAR 352.215-10, Late Proposals, Modifications of Proposals and Withdrawals of Proposals (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

Detailed information regarding the electronic process for submission of proposals may be accessed through the CMB Homepage at the following website by clicking on "E-Proposals." http://www.niaid.nih.gov/contract/default.htm

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 150 PAGES INCLUDING APPENDICES, ATTACHMENTS, OPERATING MANUALS, NON-SCANNABLE FIGURES OR DATA, LETTERS OF INTENT, ETC FOR PART A. THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 150 PAGES INCLUDING APPENDICES, ATTACHMENTS, OPERATING MANUALS, NON-SCANNABLE FIGURES OR DATA, LETTERS OF INTENT, ETC FOR PART B. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ADDITIONAL SUGGESTIONS

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

GENERAL --- To submit a proposal electronically under this RFP, Offerors will need to prepare the proposal on a word processor or spreadsheet program (for the cost portions) and convert them to Adobe Acrobat Portable Document Format (PDF). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES. Further, to expedite the file transferring process, the two files must be named using the following:

- **Technical Proposal: c:\rfp____techpropPARTA.pdf**
- **Business Proposal: c:\rfp____busipropPARTA.pdf**

AND/OR

- **Technical Proposal: c:\rfp____techpropPARTB.pdf**
- **Business Proposal: c:\rfp____busipropPARTB.pdf**

NOTE: There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0.

IF YOUR ORGANIZATION DOES NOT HAVE THE CAPABILITY TO SUBMIT ELECTRONICALLY, OR UNFORESEEN DIFFICULTIES OCCUR DURING TRANSMISSION, THE CD-ROM OR ZIPDISK PROVIDED BY YOUR ORGANIZATION WILL BE USED BY THIS OFFICE TO UPLOAD YOUR PROPOSAL INTO THE ELECTRONIC SYSEM. YOU MUST ASSURE THAT ALL VERSIONS OF THE PROPOSAL ARE IDENTICAL.

Approximately TWO weeks prior to the due date of proposals, all offerors will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contracting Officer identified in this RFP and complete and submit the attached Proposal Intent Form by the date provided on that Attachment.

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-02-19
RFP Title: Drug Development for Opportunistic Infections – Cell and Animal Model Development for Hepatitis C

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **October 15, 2001**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print):_____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

*Name of individual to whom electronic proposal instructions should be sent:

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

_____
_____
_____
_____

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Scott Drega
RFP-NIH-NIAID-DAIDS-02-19
FAX# (301) 480-5253
Email : sdrega@niaid.nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.nci.nih.gov/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the

legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

The North American Industry Classification System (NAICS) code for this acquisition is 541710.
The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10% percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

d. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that TWO (2) AWARDS will be made from this solicitation and that the award(s) will be made on/about July 15, 2002.

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a PERIOD OF PERFORMANCE OF seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

f. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

g. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

h. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

i. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

j. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

k. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However,

the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) Care of Live Vertebrate Animals

a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of

Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

b. If an Animal Assurance is already in place, the offeror's proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.

(10) Selection of Offerors

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily.

(11) Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, SECTION J, List of Attachments, is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, and HUBZone Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned, and/or HUBZone small business concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(12) HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(13) Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at:

http://www.sba.gov/size/NAICS-cover-page.htm

The Department of Commerce website for the annual determination is:

http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*__NOTE:__ FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(14) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(15) Salary Rate Limitation in Fiscal Year 2001 **

Offerors are advised that pursuant to P.L. 106-554, no NIH Fiscal Year 2001 (October 1, 2000 - September 30, 2001) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.).

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 106-554 applies only to Fiscal Year 2001 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 106-554 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

*This rate may change periodically. For your information, the rate can be found at:
http://www.opm.gov/oca/01tables/execses/html/01execsc.htm

(16) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(17) Compliance with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) As Amended by the Workforce Investment Act of 1998, Public Law 105-202 of the Americans with Disabilities Act 36 CFR Part 1194.

All Electronic and Information Technology (EIT) that is specified as deliverable in the Statement of Work (or a component of a deliverable) under this solicitation must be in compliance with Section 508. Guidelines and standards for compliance can be found in the Access Board's Final Rules at: http://www.access-board.gov/news/508-final.htm.

Any EIT products and services represented in the Electronic & Information Technology Accessibility Standards that are less than fully compliant are acceptable only if the Government has determined that there are no fully compliant products available on the open market.

For any EIT products and services, offeror's proposals must address the applicable EIT Accessibility Standards (see above for internet address).

(18) Electronic And Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

1. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

2. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, procurement, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards. Further information about Section 508 is available via the Internet at http://www.section508.gov

(19) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a) Statement of Work

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) Technical Evaluation

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) Additional Technical Proposal Information

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

a) Solicitation, contract, and/or modification number;
b) Name and address of Offeror;
c) Name and telephone number of point of contact;
d) Name, address, and telephone number of Contract Administration Office, (if available);
e) Name, address, and telephone number of Audit Office (if available);
f) Proposed cost and/or price; profit or fee (as applicable); and total;
g) The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
h) Date of submission; and
i) Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

d) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

e) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

   Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://rcb.nci.nih.gov/forms/cpi.htm

(4) Qualifications of the Offeror

a) You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(1) General Experience

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(2) Organizational Experience Related to the RFP

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) Performance History

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(4) Pertinent Contracts

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) Pertinent Grants

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(5) Other Administrative Data

a) Property

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(5) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(6) Offeror's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(7) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(8) Travel Costs/Travel Policy

a) Travel Costs - Commercial

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) Travel Policy

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors) cost/price factors and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Extent of participation of SDB concerns in terms of the value of the total acquisition.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERIA – PART A, Cell Culture Model Systems/Assays for Hepatitis C		SubWeight	WEIGHT
1.	**TECHNICAL APPROACH** The technical adequacy and feasibility of the approach presented in the technical proposal, as reflected in the documentation provided including the alternative strategies and relevant experience, for:		**65**
1(a)	Suitability of the model system and/or assay proposed for development into a drug-screening tool: • Evidence of relevance of the proposed model system and /or assay to the pathogenesis of hepatitis C liver disease; • Evidence of understanding of the anti-infective drug development process; • Adequacy of understanding of the pathobiology of hepatitis C and potential drug targets, particularly related to interpretation of preclinical drug evaluations.	**35**	
1(b)	Suitability of procedures • Appropriateness, technical design, and reproducibility of an in vitro model system and/or assay(s) proposed for inhibition of hepatitis C cellular infectivity; • Appropriateness, technical design, and reproducibility of an in vitro model system and/or assay(s) proposed for inhibition of hepatitis C viral replication; • Adequacy of statistical measures for interpretation and analyses of results; • Adequacy of measures for protection of confidential and proprietary information; • Evidence of capacity to improve, standardize and adapt new assays and techniques for determining activity of compounds against hepatitis C; • Adequacy of plans for receiving, recording and storing compounds.	**30**	
2.	**PERSONNEL QUALIFICATIONS**		**25**
2(a)	Principal Investigator: • Relevance and quality of recent work; • Demonstrated skill in developing and validating screening assays. • Demonstrated experience with technical approaches required; • Documented availability for the proposed project; • Documented experience with managing projects of similar complexity.	**15**	

2(b)	Other personnel/staffing plan • Relevance and extent of experience of other professional and research technical and support staff and their documented capability to conduct proposed studies; • Documented experience in similar projects and appropriate computer skills; • Adequacy of the staffing plan, including clear lines of authority and the time commitment of the professional and technical staff, for the conduct of the project.	**10**	
3.	**FACILITIES AND RESOURCES** (a) Documented availability of adequate facilities (suitable office, computer, and laboratory space), equipment, and resources necessary to meet the requirements of the RFP. Note: a detailed floor plan of the proposed facility that shows location of the equipment and resources to be dedicated to this project MUST be provided. (b) Adequacy of plans for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to hazardous chemical and biological agents, and safe disposal of such agents. (c) Documentation of facilities to receive and store compounds, and maintain their stability.		**10**
	TOTAL		**100**

CRITERIA – PART B, Animal Model Development for Hepatitis C		SubWeight	WEIGHT
1.	**TECHNICAL APPROACH** The technical adequacy and feasibility of the approach presented in the technical proposal, as reflected in the documentation provided including the alternative strategies and relevant experience, for:		**65**
1(a)	Suitability of the proposed animal model for use as a drug development screening tool: • Evidence of relevance of the proposed model to the pathogenesis of hepatitis C liver disease; • Evidence of understanding of the anti-infective drug development process; • Adequacy of understanding of the pathobiology of hepatitis C and potential drug targets, particularly related to interpretation of preclinical drug evaluations.	**35**	
1(b)	Suitability of procedures • Appropriateness, technical design, and reproducibility of an in vivo model system proposed for analysis of viral infectivity of organs and tissues; • Appropriateness, technical design, and reproducibility of an in vivo model system for the analysis of inhibition of viral replication; • Appropriateness, technical design, and reproducibility of an in vivo model system for the analysis of hepatitis C-induced tissue pathology; • Adequacy of statistical measures for interpretation and analyses of results; • Adequacy of measures for protection of confidential and proprietary information; • Adequacy of plans for receiving, storing, and recording compounds; • Evidence of capacity to improve, standardize and adopt new techniques for animal model development against hepatitis C and an immunocompromised setting.	**30**	
2.	**PERSONNEL QUALIFICATIONS**		**25**
2(a)	Principal Investigator: • Relevance and quality of recent work; • Demonstrated skill in developing and validating animal models. • Demonstrated experience with technical approaches required; • Documented availability for the proposed project; • Documented experience with managing projects of similar complexity.	**15**	

2(b)	Other personnel/staffing plan • Relevance and extent of experience of other professional and research technical and support staff and their documented capability to conduct proposed studies; • Documented experience in similar projects and appropriate computer skills; • Adequacy of the staffing plan, including clear lines of authority and the time commitment of the professional and technical staff, for the conduct of the project.	**10**	
3.	**FACILITIES AND RESOURCES** (a) Documented availability of adequate facilities (suitable office, computer, and laboratory space), equipment, and resources necessary to meet the requirements of the RFP. Note: a detailed floor plan of the proposed facility that shows location of the equipment and resources to be dedicated to this project MUST be provided. (b) Adequacy of plans for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to hazardous chemical and biological agents, and safe disposal of such agents. (c) Documentation of facilities to receive and store compounds, and maintain their stability.		**10**
	TOTAL		**100**

Attachment A

Protection of Proprietary Data

Information and data provided to or generated by the Contractor under this Contract shall be treated confidentially and protected by an Advance Understanding to be included in the resulting contract and worded as follows:

"Because there is a likelihood that the Contractor will be utilizing and evaluating materials provided to the Government by a third party Supplier, it is essential to include provisions that will protect the proprietary rights of the Supplier. These materials generally are supplied to the Government under conditions outlined in NIAID's standard Screening Agreement or other appropriate documents. The Contractor shall be bound by the same terms and conditions as the Government in these agreements, with respect to the proprietary and confidential nature of the information provided by the Supplier.

All information provided by the Supplier or Project Officer should be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. Confidential information may not be revealed without written permission. All materials supplied to the Contractor and all test results similarly are to be considered confidential. All materials supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials will be permitted.

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for review by the NIAID Project Officer before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts/abstracts in a period of time not to exceed 60 calendar days from receipt, and will either agree to the publication/disclosure, recommend changes and, as applicable, refer the document to the Supplier of the compound for their review. When the Supplier does not consent to publication of the manuscript or abstract, the Project Officer shall notify the Contractor and NIAID Contracting Officer. The Project Officer is responsible for ensuring that all parties adhere to the terms and conditions of any existing Screening Agreement, Material Transfer Agreement, or other agreements between NIAID and the Supplier. NIAID will use its best efforts to assist and expedite the review process by the Supplier.

Should patents arise from this contract, they will be subject to federal law governing inventions. Every patent applicant (individual or institutional) is required to provide the Government with a non-exclusive, irrevocable, paid-up license to the invention."

ATTACHMENT B

Screening Agreement for Submitting Products to the Division of Acquired Immunodeficiency Syndrome (AIDS), National Institute of Allergy and Infectious Diseases, hereafter referred to as the DIVISION,

by

_____ , hereafter referred to as the SUPPLIER.

1. *The SUPPLIER may supply products, patented or unpatented, to the DIVISION which may proceed to screen and test for possible treatment for AIDS and associated opportunistic infections including tuberculosis. These products are to be used for screening and testing as anti-viral, anti-bacterial, anti-fungal, anti-parasitic, immunomodulating, and biological modifying agents with potential for the treatment of AIDS and associated infections, and for no other purpose.*

Using protocols evaluated and approved mutually by the DIVISION and the SUPPLIER, the products will be screened by one or more of the DIVISION's contract testing laboratories, or in any other testing laboratories which may from time to time be added to the DIVISION's portfolio but in any event will not be placed in the laboratories of any company in the pharmaceutical or chemical industries without the SUPPLIER's written permission.

2. *In order to facilitate records keeping and handling of confidential materials, the DIVISION utilizes the following procedures:*

    a. *The SUPPLIER shall forward to the DIVISION the products to be tested together with data sheets in duplicate for each product, giving pertinent available data as to chemical constitution, solubility, toxicity, previous biological efficacy and any precautions which need to be followed in handling, storing, and shipping.*

    b. *It is clearly understood that no data about the products and the results of the testing will be kept in files open to the public either by the DIVISION, the testing laboratories, or the data processing activities. Only those employees directly engaged in the operation of the DIVISION will have access to the files of information regarding source and nature of confidential materials and results of testing, except as required pursuant to the Freedom of Information Act, 5 U.S.C.552.*

    c. *Whenever possible the SUPPLIER will be given the choice of the DIVISION's contract testing laboratories, although at present there is no preference; and it is understood that the DIVISION reserves the right to send the SUPPLIER's products to another screening contractor if the need arises. It is furthermore understood that the contracts between the DIVISION and the testing laboratories will contain provisions to safe guard the SUPPLIER's rights under this Agreement.*

    d. *Because the DIVISION's screening effort will be accomplished in collaboration with the DIVISION's scientific staff and academic collaborators, as well as the SUPPLIER's own staff, the DIVISION will work in concert to assure rapid ongoing communications of screening data to the SUPPLIER, and the SUPPLIER will in turn use its best efforts to keep the DIVISION informed on the SUPPLIER's own ongoing concomitant studies.*

3. *Although the SUPPLIER recognizes that the interchange of information is generally desirable in the field of treatment for AIDS, it is mutually understood that the SUPPLIER, in voluntarily supplying appropriately marked information deemed proprietary, including product and information regarding this product hereunder, is entitled to protection for any such technical information it may furnish.*

    a. *It is understood and agreed to, subject to applicable law, that the SUPPLIER shall retain all rights to those compounds or products in which the SUPPLIER has a proprietary interest. The SUPPLIER understands that contractors have the right to elect to retain title to inventions made under NIAID-supported contracts [37 CFR 401.14(b)]. The SUPPLIER deserves the right to reach an agreement with these contractors concerning the disposition of these intellectual property rights. The DIVISION agrees to notify the SUPPLIER of the names of the contractors prior to submitting compounds or products to them. Subject notwithstanding, to the provision that, with respect only to those drugs which have been determined by means of the various screening and testing processes to possess such significant activity (strong potential to be scheduled for clinical trial by the DIVISION, using mutually approved protocols), the Government shall have a royalty-free, irrevocable, nonexclusive license for clinical trials under any patent which the SUPPLIER may have or obtain on such compound or product or on a process for use of*

such compound or product, to manufacture and/or use by or for the Government the invention(s) claimed by the patent(s) only for medical research purposes related to or connected with the treatment of AIDS and associated infections including tuberculosis.

b. The DIVISION agrees that the publication of biological data on products provided by the SUPPLIER is worthwhile and shall be encouraged. Specifically:

(1) With regard to screening results on compounds in which the SUPPLIER has a proprietary interest, and that the DIVISION deems significant for the research on therapies for AIDS and associated infections including tuberculosis, the SUPPLIER agrees that the DIVISION may publish or otherwise publicly disclose such results after a period of 6 months from the date of final reporting of screening and testing results to the SUPPLIER in order for patent applications to be filed. The DIVISION will consult with the SUPPLIER prior to publication within this period on screening and testing results.

(2) For all other compounds, the SUPPLIER will consult with the DIVISION prior to publishing screening data along with the available biological and physical data; such consent shall not be unreasonably withheld.

(3) In no case will the DIVISION publish information identifying the SUPPLIER as the source of the compound without written approval.

c. As soon as tests are completed and reported to the DIVISION, the SUPPLIER will receive from the DIVISION a full report including all screening data. The products scheduled for clinical trial, referred to herein, shall be designated by the DIVISION, and the aforementioned report will specify the compounds so selected. The DIVISION shall be consulted whenever the SUPPLIER desires to include screening data in a publication, and appropriate credit shall be given to the U.S. Public Health Service.

The DIVISION is confident that this agreement will lay the basis for mutually satisfactory cooperation in the field and in the treatment of AIDS and associated diseases.

In agreeing to the above, the SUPPLIER signs below, as well as the attached duplicate of this agreement, and returns both to the DIVISION for countersignature. One original will be returned for the SUPPLIER's files.

_____	_____
Director, Division of AIDS NIAID, NIH	Name (Signature)
_____	_____
Date	Title
	_____
	Organization
	_____
	_____
	Address
	_____
	Date